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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/670,100 | 09/24/2003 | Kenneth D. Fine | FINE 01936 C1US | 7188 |

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| EXAMINER | |
|---|---|
| NGUYEN, BAO THUY L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | |

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/670,100 | FINE, KENNETH D. | |
| | Examiner | Art Unit | |
| | Bao-Thuy L. Nguyen | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**1.** In response to the election/restriction dated 22 June 2006, Applicant canceled claims 15-34 and 38-64 and amends all pending claims to depend from and further limit claim 1.

**2.** Claims 1-14 and 35-37 are pending.

### *Claim Rejections - 35 USC § 112*

**3.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the recitation of two distinct diagnosing steps. It appears that the step of diagnosing an ailment related to the immunologic food sensitivity does not correlate with the preamble. Because there are two distinct diagnoses recited, the metes and bounds of the claim is difficult to ascertain.

Claim 2 states a method where a concentrating step is performed on the fecal sample to obtain a testing portion without further elaborating on exactly what steps are involved in a concentrating step. Claim 8, however, states that the fecal sample is

concentrated by centrifuging an removing the supernatant portion of the centrifuged fecal sample. It is unclear how the supernatant portion of the centrifuged sample can be considered a "concentrated sample". According to Webster's dictionary, "concentrate" means to increase the concentration of a solution or mixture. In the instant case, it appears that the centrifuging step only serve to separate a solid from a liquid portion of a test sample and has nothing to do with "concentrating" the fecal sample.

Claims 6 and 7 are vague because it appears to enlarge the scope of claim 1 from which they depends. Claim 1 recites the detection of IgA; however, claims 6 and 7 recite the detection of "an antibody".

Claim 11 is vague and indefinite because it si unclear what amount of the fecal sample would be considered to be "about equal" to an amount of diluted serum required by standard use of an ELISA kit because it is unclear what type of kit is used. In other words, there are a plethora of ELISA kits available commercially and without appropriate guidance as to the exact specification of each of the kit, how would one determine the baseline or standard amount to use?

Claims 12 and 14 are confusing because the step of concentrating involves freeze-drying and then reconstituting the freeze-dried material in water to form a testing portion. If anything, this appears to be diluting and not "concentrating" a sample.

Claims 35-37 do not further limit claim 1 from which they depends. Claim 1 is a method for diagnosing a food sensitivity by performing an immunoassay to detect IgA

specific to a particular food. As such, claims 35-37 neither limits the immunoassay steps nor do they limit the food sensitivity to a specific type.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8-10, 12-14 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolmannskog et al (Int. Archs Allergy Appl. Immun. Vol. 76. Pages 133-137. 1985).

Kolmannskog discloses diagnosing food allergy using immunoassays to detect IgE, IgA, IgG, IgM and albumin in both serum and feces to specific allergen. Kolmannskog discloses extracts of freeze-dried feces reconstituted in phosphate-buffered saline and the supernatant was used in the assay.

Kolmannskog differs from the instant invention in failing to specifically teach the size and consistency of the sample. However, such a sample is seen to be obvious because it has long been settled to no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. Since Applicant has not disclosed that the specific limitations recited in the instant

claims are for any particular purpose or solve any stated problem and the prior art as well as the specification, teaches that other sample sizes may be used, and the amount is often varied according to the sample being analyzed, any appropriate amount of a testing portion depends on the requirements of an assay, appears to work equally well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by Kolmannskog by normal optimization procedures known in the art.

Furthermore, even though the reference does not specifically state the consistency of the fecal sample, one of ordinary skill in the art would have had a reasonable expectation of success in detecting analytes in samples with varied amount of solid to liquid material. It would appear that the make-up of the fecal sample does not negatively or positively impact a method of detecting any antibodies that may be present in them as alluded to the prior art of record.

**4.** Claims 1-11 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hass et al. (Clinical Chemistry. Vol. 39, No. 4, pages 696-967. 1993).

Hass discloses an ELISA for fecal AGA IgA in patients suffering from celiac disease. Collected samples are frozen before use and reconstitute in buffer. Supernatant obtained by centrifugation was used to determine IgA using a commercial sandwich ELISA assay.

Even though Hass does not specifically teach using a sample of about 20g, nor does it disclose the consistency of the fecal sample, such a sample is seen to be obvious because it is no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. Since Applicant has not disclosed that the specific limitations recited in the instant claims are for any particular purpose or solve any stated problem and the prior art as well as the specification, teaches that other sample sizes may be used, and the amount is often varied according to the sample being analyzed, any appropriate amount of a testing portion depends on the requirements of an assay, appears to work equally well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by Kolmannskog by normal optimization procedures known in the art. Furthermore, even though the reference does not specifically state the consistency of the fecal sample, one of ordinary skill in the art would have had a reasonable expectation of success in detecting analytes in samples with varied amount of solid to liquid material. It would appear that the make-up of the fecal sample does not negatively or positively impact a method of detecting any antibodies that may be present in them as alluded to the prior art of record.

### *Double Patenting*

**5.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**6.** Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,667,160. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a method for diagnosing an immunological food sensitivity comprising the steps of collecting a fecal sample, screening the fecal sample to detect the presence of an IgA antibody to a particular food substance; and diagnosing an immunologic food sensitivity based on the presence of the antibody. Even though the '160 patent does not specifically teach the diagnosing an ailment related to the food sensitivity, this ailment can been seen as an obvious allergic reaction to certain type of food.

*Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 10/10/06